REMARKS

Claims 1-18, 77-84, and 91-93 are pending in this application. New claims 94-96 are drawn to embodiments of the invention. No new matter has been added.

Rejections under 35 U.S.C. §112

The Office Action rejected claim 3 as allegedly indefinite. Applicants respectfully traverse this rejection. A derivative is defined by Meriam-Webster Dictionary as "a chemical substance related structurally to another substance and theoretically derivable from it". Changes necessary to constitute a derivative, or chemical analog, are commonly known in the art and are not believed to warrant further definition. Therefore, Applicants respectfully request that this rejection be withdrawn.

The Office Action rejected claims 1, 18, 77, 80 and 91 as allegedly indefinite. The Office Action states that the claims and specification do not disclose an explicit numerical value as to what constitutes an "effective amount" of a pharmaceutically acceptable carrier or what a side effect is. Applicants respectfully submit that the Office Action is in error. The definiteness of a claim language must be analyzed, not in a vacuum, but in light of (1) the content of the application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing ordinary skill in the art at the time of the invention. See, e.g., *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 USPQ 1 (Fed. Cir. 1984); *W. L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). A claim is not indefinite simply because it is hard to understand when viewed without the benefit of the specification. *S3 Inc. v. nVidia Corp.*, 259 F.3d 1364, 59 USPQ 2d 1745 (Fed. Cir. 2001). Further, the term "effective amount" is a "common and generally acceptable term for pharmaceutical claims, and is not ambiguous or indefinite, provided that person of ordinary skill in art could determine specific amounts without undue experimentation". *In re Halleck*, 422 F.2d 911 (CCPA 1970), which is approved by *Geneva Pharmaceuticals, Inc. v. Glaxo SmithKline PLC*, 349 F.3d 1373, 68 USPQ2d 1865 (Fed. Cir. 2003).

In this instance, the effective amount of a pharmaceutically acceptable carrier is described with sufficient clarity that one of skill in the art would understand what is meant by an effective amount and would be able to determine, for a given usage, what an effective

amount of a pharmaceutically acceptable carrier would be, without undue experimentation. Further, examples are given in paragraphs 21 and 51 of the specification indicate that in liquid form, 0.1 to 25% by weight albumin or HSA may be used.

The same is true with respect to side effects. One of skill in the art, based on the disclosure, would be able to identify side effects associated with administration, based on his knowledge of the nature of the pharmaceutical agent being administered. Further, paragraphs 3, 17, 37, and 70 disclose side effects associated with administration, examples of which include venous irritation, phlebitis, pain upon injection, as well as side effects caused by various solubilizing agents and emulsions that may be irritating, allergenic or toxic. Therefore, Applicants respectfully submit that what constitutes an effective amount of a pharmaceutically acceptable carrier and a side effect as claimed are fully disclosed by the specification and are not indefinite. Applicants respectfully request that the rejection be withdrawn.

The Office Action rejected claims 5-6, 10-11, 17, 77-82, 84, and 91-93 as allegedly indefinite; the Office Action objects to the use of the word "about". Applicants respectfully submit that the Office Action is in error. The term "about" should be interpreted in the context of the invention and is intended to encompass the range of experimental error that occurs in any measurement and that one of skill in the art would readily understand the range that is intended to include. *BJ Services Co. v. Halliburton Energy Services, Inc.*, 338 F.3d 1368, 67 USPQ2d 1692 (Fed. Cir. 2003). Therefore, Applicants respectfully submit that the use of the term "about" does not render the instant claims indefinite, and respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 102(b)

The Office Action rejected claims 1-2, 5, and 18 as allegedly anticipated by Yang, et al. (Alkylation of human albumin by the antimalarial atemisinin, 1993 *Biochem. Pharm.* 46(2): 336-339) Applicants respectfully traverse this rejection. Yang, et al. teach an incubation mixture used in a binding assay. In Yang, et al., albumin is bound to artemisinin and in one aspect of the assay, deferoxamine is utilized to assess the binding. Nowhere in Yang et al. is there described a pharmaceutical composition suitable for administration to a human, which will reduce side effects associated with administration. There is no teaching to combine albumin, atemisinin and deferoxamine in one pharmaceutical composition or to use

it as a treatment. Further, there is no suggestion that the preparations utilized in Yang, et al. would be suitable for administration to a human. Therefore, Yang, et al. do not disclose each of the claimed elements. In view of this, Applicants request that the rejection be withdrawn.

The Office Action rejected claims 1, 5-6, 9-11, and 18 as allegedly anticipated by Ritov, et al. (Hexokinase isozyme distribution in human skeletal muscle, 2001 *Diabetes* 50: 1253-1262). Applicants respectfully traverse. Ritov, et al. teach a homogenation medium comprising bovine serum albumin (BSA) and DFO to wash out blood from muscle tissue samples (pg. 1424, paragraphs 4-5). It does not disclose a pharmaceutical composition suitable for administration to a human, which will reduce side effects associated with administration. As indicated, Ritov, et al.'s preparation utilizes BSA. It is well known in the art that bovine serum albumin is not acceptable for use in humans due to adverse immunological reactions. Accordingly, the medium taught by Ritov, et al. is clearly not pharmaceutically acceptable for use in a human. Therefore, this reference does not teach every element of the relevant claims and Applicants request that this rejection be withdrawn.

The Office Action rejected claims 77-83, and 91-93 as allegedly anticipated by Paal, et al. (High affinity binding of paclitaxel to human serum albumin, 2001 *Eur. J. Biochem.* 268: 2187-2191). Applicants respectfully traverse this rejection. According to the Office Action, Paal, et al. teach albumin bound to paclitaxel in a ratio required by the instant claims. However, Paal, et al. teach a binding assay not a pharmaceutical composition. There is no teaching in Paal, et al. to administer the preparation to a human as required by claims 77-79 and 91-93. Further, there is no teaching in Paal, et al. of a pharmaceutical composition with an acceptable carrier in an amount effective to increase transport of a drug to a site of infirmity in a human as required by claims 80-83. Therefore, Paal, et al. do not teach every element of the instant claims. In addition, new claims 94-96 are not anticipated by Paal, et al. as they do not include paclitaxel. In view of the above, Applicants request that this rejection be withdrawn.

Double Patenting Rejection

The Office Action provisionally rejected claims 77-79, and 91-93 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-4 of copending Application No. 10/616,709. Applicants respectfully traverse this rejection. Claims 1-4 of the '709 application do not claim a pharmaceutical composition with a ratio of

protein, such as albumin, to pharmaceutical agent that is 18:1 w/w or less. Further, as the claims of the '709 application do not render obvious the instant claims which are drawn to a composition that reduces side effects associated with administration. Therefore, Applicants respectfully request that this rejection be withdrawn.

Conclusion

The application is in good and proper form for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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Date: June 16, 2005

Amendment or ROA - Regular (Revised 2005 05 11)